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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,452	03/15/2007	Andreas Greinacher	30572/42052	2103

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,452	GREINACHER ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *5-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-4 and 10-11) in the reply filed on May 17, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/17/2010.

Status of Claims

2. Claims 1-11 are pending. Claims 1-4 and 10-11 are elected (see para. 1 above).

Claim Objections

3. Claims 10-11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 01/11/2007 is acknowledged and has been reviewed.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant should note that prophylaxis is interpreted as prevention therefore necessitating the rejection below.

Claims 1-4 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating acute coronary syndrome, angina pectoris, cardiac infarction does not reasonably provide enablement for prophylaxis of cardiovascular disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

Nature of the invention.

The nature of the invention is directed to treating and/or prophylaxis of cardiovascular disease with the use of an inhibitor of the multidrug resistance protein (MRP4). As stated, however, claim 1 includes within its scope a wide variation of cardiovascular diseases that may or may not be prevented.

State of the prior art and the predictability or lack thereof in the art.

The state of the prior art is that is that dipyridamole plus aspirin failed to establish non-inferiority with clopidogrel in preventing second strokes, even though the study found little difference between the drugs in effectiveness (see enclosed Medpage Today).

Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would first need to determine the type of conditions in other to carry out prophylaxis in the patient.

Amount of direction and guidance provided by the inventor.

The amount of direction or guidance present is not sufficient to show prophylaxis of a wide variation of cardiovascular diseases. The gap between the teaching in the specification of *in vitro* activity and *in vivo* is large enough to warrant thorough and compelling *in vivo* data

especially in the absence of working examples demonstrating the full scope of prophylaxis of cardiovascular diseases.

Existence of working examples.

As discussed above, the working example found on **pages 10-24** fails to reasonably correlate to prophylaxis treatment of a wide variation of cardiovascular disease. Applicant's omission of working examples does not enable one of ordinary skill in the art to treat the numerous amounts of diseases encompassed by the instant invention.

Breadth of claims.

Claim 1 is extremely broad due to the vast number of possible diseases encompassed by the instant invention.

Thus the current claims are not commensurate in scope with the limited guidance provided in the specification, and therefore, would require undue experimentation for the skilled artisan to reasonable discover how to make the currently claimed invention work.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear whether all the compounds recited in claim 4 are required at the same time for the treatment of cardiovascular disease or is intended to alternatively be a Markush group.

Regarding claim 4, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. Claims 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites "the use of a substance identified by the process...of claims 4-7..." however claim 4 does not recite a process, thereby being indefinite.

Claim 10 recites the limitation "the use of a substance identified by the process...of claims 4-7..." in claim 4. There is insufficient ante35 U.S.C. 101 reads as follows:

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 and 10-11 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

This claim is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*,

255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). The term "use of" is not among the statutory class of inventions.

However in order to advance prosecution, this claim will be treated as a method claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Heidland et al. (American Heart Journal 139(3) 2000, Mosby Inc.)

Heidland et al. teach treating cardiovascular disease (i.e., intracoronary stent placement or balloon angioplasty, myocardial infarct) with the active agent (i.e., dipyridamole, as required by instant claims 1-2, 4 and 10-11). Because Heidland teaches treating cardiovascular disease with dipyridamole, it is reasonable that dipyridamole is an inhibitor of the multi-drug resistance protein MRP4 in platelets because as stated in the MPEP 2112.01"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) and therefore would also reasonably have a molecular weight of about 200-1000 Daltons and would inhibit the MRP4-mediated transport as required by instant claim 3.

10. Claims 1-4 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Cross et al. (US 4,217,357).

Cross et al. teach treating cardiovascular disease (i.e., ischaemic heart disease (i.e., stroke)) with the active agent (i.e., dipyridamole, as required by instant claims 1-2 and 4). Because Heidland teaches treating cardiovascular disease with dipyridamole, it is reasonable that dipyridamole is an inhibitor of the multi-drug resistance protein MRP4 in platelets because as stated in the MPEP 2112.01"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) and would also have a molecular weight of about 200-1000 Daltons and would inhibit the MRP4-mediated transport as required by instant claim 3.

11. No claim is allowed**.**

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
5/29/10

/Robert C. Hayes/
Primary Examiner, Art Unit 1649